

Attorney Docket No.: **KUZ0029US.NP**  
Inventors: **Shirai et al.**  
Serial No.: **10/575,562**  
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**REMARKS**

Claims 1-3 and 7-10 are pending in the instant application. Claims 1-3 and 7-10 have been rejected. Claims 1, 2, 8, 9 and 10 have been amended. Claims 3 and 7 have been canceled. New claims 11-17 have been added. Support for these amendments is provided in the original claims as well as the specification at, for example, paragraphs [0001], [0004], [0008], [0010] and [0050]-[0056]. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Finality of Office Action**

The Examiner has been made final the Office Action mailed March 24, 2010. Reconsideration of the finality of this Office Action as being premature in accordance with MPEP 706.07(c) is respectfully requested.

MPEP 706.07 is clear:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoid all the grounds of rejection and objection.

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Further, MPEP 707.06(a) states that:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new grounds of rejection that is not necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

The instant Office Action, indicated to be final by the Examiner, raises rejections based on newly cited art not included in an IDS submitted by Applicants. Applicants respectfully disagree with the Examiner that these new grounds of rejection under 35 U.S.C. 103(a) were necessitated by Applicants' amendment of December 21, 2009.

In the Advisory Action mailed June 24, 2010, the Examiner states that the previous rejection was properly made final since applicants' amendments to the claims changed the scope of the claims by introducing new ranges in element (d) of claim 1 and properties (last line of claim 1), and therefore required a new search and consideration at that time.

Applicants respectfully disagree as the "new range" in element (d) was a narrower range within the broader range originally claimed. Further, the recited property of removal resistance in water is a property exhibited by

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percutaneous absorption preparations of both the broader range originally claimed and the narrower range set forth in the amendment filed December 21, 2009.

Accordingly, Applicants respectfully submit that the references of Nakamura (U.S. Patent 5,770,221) and Yamamoto (U.S. Patent 5,429,591) should have been revealed in the search for the first action as the amended claims with a narrower range and property exhibited by preparations of the broader and narrower range were clearly part of the invention as originally disclosed and claimed. Citation of these references for the first time in a final office action clearly fails to provide for development of a clear issue between the examiner and applicants as well as an opportunity for applicants to reply to this action by amendment entered by right.

Accordingly, reconsideration and withdrawal of this premature final rejection in accordance with MPEP 706.07(d) and entry of the amendments submitted herewith without requiring the RCE and fee provided herewith is respectfully requested.

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**II. Rejection of Claims 1-3 and 7-10 under 35 U.S.C. 112,  
first paragraph - Written Description**

Claims 1-3 and 7-10 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the ratio of (15-50)/(25-50)/(30-50) is new matter as written description support is lacking for this recited ratio.

Applicants respectfully traverse this rejection.

Applicants believe that the broader ratio set forth at paragraph [0010] provides adequate written support for the narrower claimed ratio.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to recite the ratios "(10-60)/(10-50)/(20-60)" in accordance with the original claims and teachings in paragraph [0010] of the instant specification and added new claim 13 which recites the ratios of "(15-50)/(25-45)/(30-50)" acknowledged by the Examiner to be supported in the instant application.

Withdrawal of this rejection is respectfully requested.

**III. Rejection of Claims under 35 U.S.C. 112, second  
paragraph**

Claims 1-3 and 7-10 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that recitation of "petroleum type resin" is indefinite.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have deleted the phrase "petroleum type resin" from claim 1. New claim 12 recites that the tackifier is petroleum resin.

Withdrawal of this rejection is respectfully requested.

#### **IV. Rejection of Claims under 35 U.S.C. 103(a)**

Claims 1-3 and 7-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (U.S. Patent 5,770,221) in view of Yamamoto et al. (U.S. Patent 5,429,591).

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the claims have been amended to recite a percutaneous absorption preparation which comprises:

- (a) one or more drugs, and
- (b) polyisoprene,
- (c) a styrene/isoprene/styrene copolymer, and
- (d) solid polyisobutylene, in a proportion of (10-60)/(10-50)/(20-60) parts by weight relative to the total

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weight of (b), (c) and (d) and further contains a non-solid isobutylene polymer and a tackifier, characterized in that the amount of the non-solid isobutylene polymer is 5 to 25 parts by weight per 100 parts by weight of the sum of (b), (c) and (d), wherein the content of the tackifier is in a proportion of 10-80 parts by weight relative to the total weight of (b), (c) and (d), thereby exhibiting a removal resistance to water. Support for this amendment is provided in the original claims and in paragraph [0001] of the specification wherein it is taught that the invention relates to an adhesive patch for external use on the skin which includes a percutaneous absorption preparation.

In contrast, Nakamura describes a formulation for percutaneous administration for treating disturbances in micturition acknowledged by the Examiner **not** to comprise polyisoprene.

Further, Yamamoto describes a dressing for wounds and treatments of incontinence and artificial anuses, not a percutaneous absorption preparation. Made clear in paragraph [0001] of the instant application is that percutaneous absorption preparations and surgical dressings are considered separate types of uses for adhesive patches. Accordingly, Applicants do not believe that the teachings of

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Yamamoto et al. relating to wound dressings are relevant to the instant claimed percutaneous absorption preparations or to the formulations of Nakamura.

In particular, Yamamoto describes "where the rubber-based adhesive contains polyisobutylene, it is known that the backbones of the polyisobutylene may be decomposed by irradiation, causing the adhesive composition possibly to liquefy and flow out. Yamamoto, and not Nakamura as suggested by the Examiner at page 6 of the Office Action, teaches that in order to prevent such a phenomenon, it is preferable that a polymer which, upon irradiation, undergoes not a degradation reaction but a crosslinking reaction, such as natural rubber, polyisoprene . . . is added to the adhesive layer . . . Preferred of these irradiation-crosslinkable polymers are polyisoprene . . ." (column 4, line 64-column 5, line 13).

The Examiner suggests that one would have been motivated to add from 3-20% by weight polyisoprene (taught to preferable by Yamamoto) to Nakamura's composition to prevent decomposition of the polyisobutylene during sterilization.

Applicants respectfully disagree with the Examiner's suggested motivation for combining these references as there

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is no discussion whatsoever in Nakamura et al. regarding sterilization and/or a lack of stability and/or decomposition of their formulations for percutaneous administration for treating disturbances in micturition.

Nor would the skilled artisan expect there to be such discussion in a reference for formulations for percutaneous administration of a drug. While  $\gamma$ -ray and electron beam sterilization techniques may be useful for wound dressings such as taught by Yamamoto, these sterilization techniques result in decomposition of many drugs including those listed in claim 8 and 11 of the instant application. Thus, such sterilization techniques are not routinely used in percutaneous absorption preparations.

Accordingly, the Examiner's suggested motivation to add from 3-20% by weight polyisoprene (taught to preferable by Yamamoto) to Nakamura's composition to prevent decomposition of the polyisobutylene during sterilization is incorrect since such sterilization techniques are not taught to be used by Nakamura nor routinely used in development of percutaneous absorption compositions comprising one or more drugs.

Thus, as there is no teaching or suggestion or motivation to combine the cited references of Nakamura and

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Yamamoto, the cited combination of references can not establish a prima facie case of obviousness with respect to the instant claimed invention. See MPEP 2143.01

Further, the instant specification states, "By adopting polyisoprene and solid polyisobutylene as rubber ingredients in a pressure-sensitive adhesive composition of the invention, a soft pressure-sensitive adhesive feeling and removal feeling can be obtained, while there is no uncomfortable sticky feeling and irritation to the skin is reduced . . . it becomes soft as polyisoprene and solid polyisobutylene increase" (see paragraph [0008]) and "a soft pressure-sensitive adhesive feeling and removal feeling are afforded." (see paragraph [0010]). The properties are also evidenced in the Examples beginning at page 16 of the instant application. In particular, Applicants direct the Examiner to page 28 through 29 where results of the finger tack test are presented demonstrating tackiness and use feeling of the instant claimed compositions to be excellent. In contrast, Comparative Example 1, which contains no polyisoprene, exhibited unacceptable characteristics as a hard adhesive mass causing pain. These demonstrated softening properties and decreases in uncomfortable stickiness and irritation are clearly not a result of

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crosslinkage upon irradiation as taught by Yamamoto et al. to prevent liquefying and flow out of the adhesive compositions and are completely unexpected over the combined teachings of Nakamura et al. and Yamamoto et al. The evidence of these unexpected properties set forth in the instant specification rebuts any *prima facie* case of obviousness over the combined teachings of Nakamura et al. and Yamamoto et al. See MPEP 2145.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

**V. New Claim 17**

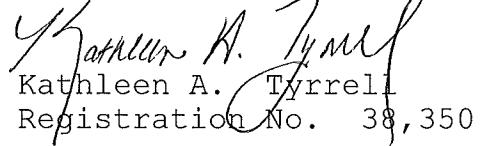
MPEP 821.04(b) states: [w]here the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, applicant may present claims directed to the process of making and/or using the allowable product by way of amendment. It is believed that the pending product claims are in condition for allowance. Accordingly, joinder and allowance of claim 17, drawn to a process for using the claimed product, is respectfully requested.

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**VI. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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